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August 23, 1999

FOOD AND DRUG ADMINISTRATION
Dockets Management Branch HFA-305
12420 Parklawn Dr., Room 1-23
Rockville, MD 20857
Attn: Docket Number 95S-0158

Subject: BB IND-7371
Disclosure of study results, Protocol AHS02.

To Dockets Management Branch:

Reference is made to our Investigational New Drug Application for Humanized Monoclonal Antibody Hu23F2G for Hemorrhagic Shock, BB-IND 7371, which was originally submitted to the FDA Office of Therapeutics Research and Review on October 28, 1997. We also refer to:

i) Protocol AHS02, entitled "Phase 2B Safety and Efficacy Study of Hu23F2G in Subjects with Hemorrhagic Shock" which was included in the original submission

ii) The guidelines described in 21 CFR §312.54(a) which require that IRB information concerning public disclosure be submitted to Docket 95S-0158, for clinical investigations involving an exemption from informed consent under 21 CFR§50.24.

The purpose of this submission is to provide documentation (21 CFR§50.24(a)(7)(iii)) concerning public disclosure following completion of Protocol AHS02. The template included in this submission was provided by ICOS (the study sponsor) to all of the sites that participated in this trial. Individual site IRBs will use this template to apprise the communities, and researchers of the completed study, including demographic characteristics of the research population, and the study results.

If you have any comments or questions regarding this submission, please do not hesitate to contact me at (425) 485-1900, extension 2297.

Sincerely,

Jeff Hesselberg, M.B.A.
Associate Director, Regulatory Affairs

95S-0158

Supp9

Trauma Study Results

Hospital/Institution recently participated in a research study to evaluate an investigational drug that may help severely injured patients. The investigational drug being tested is called Hu23F2G (LeukArrest™). The research study is sponsored by ICOS Corporation (Bothell, Washington). Hu23F2G acts on the white blood cells and may prevent them from causing damage to the body's major organs following trauma. In order to determine the safety and effectiveness of this new drug, researchers studied 150 trauma victims at 11 trauma centers throughout the United States. In the clinical trial, some patients received Hu23F2G along with standard care and some patients received the standard care for severe injury alone.

Patients were enrolled into the study in one of three ways. First, patients gave their own informed consent if they were able. Second, if a patient were unable to give consent, then upon arrival in the emergency department the hospital staff attempted to reach a family member. If this was successful, the family was asked to provide informed assent. Third, if a family member was not located within three hours, the patient was enrolled under the Food and Drug Administration (FDA) regulations waiving the requirement to obtain an informed consent. The effort to locate and inform family continued after the patient had been enrolled into the study under the FDA regulations waiving the requirement to obtain an informed consent. Use of the FDA regulations waiving the requirement to obtain an informed consent in this study was approved by the FDA and the *Institution IRB*, which is charged with ethical oversight of patient research at *Hospital/Institution*.

Enrollment into this study was completed on January 26, 1999. Across the entire study, 14% of patients signed their own consent, 53% had a family member provide informed assent and 33% were enrolled with waiver of informed consent. At *hospital/institution*, *number* patients were enrolled into the study from *date* to *date*. *number* patients signed their own consent, *number* had a family member provide informed assent, and *number* patients were enrolled with a waiver of informed consent.

In this study, the average patient age was 36 years old, males were enrolled about twice as often as females. The majority of the patients were Caucasian (58%), followed by African American (25%) and other races (17%). At *Hospital/ Institution* the average patient age was _____ years old, _____ males and _____ females were enrolled. The majority of the patients were Caucasian (____), followed by African American (___) and other races (____).

Preliminary analysis of the study has been performed. Hu23F2G appeared to be safe in this patient population. A total of 11 patients (7%) died in the study. The death rate was 10% in patients who received standard of care alone and 6% in patients who received Hu23F2G. Although the endpoints that the study was designed to measure were no different between the patients that received standard of care and the patients that received Hu23F2G along with standard of care, there was a suggestion that those patients who received the higher dose of Hu23F2G had decreased heart and lung failure compared with those patients who received standard care only. Further analyses of the data are underway.

Any questions about this study should be directed to *investigator name and phone number.*

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Sender's Name Jeff Hesselberg, M.B.A. Phone (425) 485-1900

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2 Your Internal Billing Reference Information

3 To

Recipient's Name Food & Drug Administration Phone (301) 827-6860

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